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**PRE-APPEAL BRIEF REQUEST FOR REVIEW**

Docket Number (Optional)

080652-0517

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On

Signature

Typed or printed name

Application Number

10/612648

Filed

7/2/2003

First Named Inventor

Dallas L. Cloutre

Art Unit

1618

Examiner

Zohreh A. Fay

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).

Note: No more than five (5) pages may be provided.

I am the

☐ applicant/inventor.

☐ assignee of record of the entire interest.

See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)

☒ attorney or agent of record.

Registration number 58,468

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☐ attorney or agent acting under 37 CFR 1.34.

Registration number if acting under 37 CFR 1.34

January 8, 2008

Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below\*.

☒ \*Total of 1 forms are submitted.

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***IN THE UNITED STATES PATENT AND TRADEMARK OFFICE***

Applicant: Dallas L Clouatre  
Title: (-)-HYDROXYCITRIC ACID FOR  
CONTROLLING INFLAMMATION  
Appl. No.: 10/612648  
Filing Date: 7/2/2003  
Examiner: Zohreh A. Fay  
Art Unit: 1618  
Confirmation 3676  
Number:

**PRE-APPEAL BRIEF REQUEST FOR REVIEW**

Mail Stop AF  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

In accordance with the New **Pre-Appeal Brief Conference Pilot Program**, announced July 11, 2005, this Pre-Appeal Brief Request is being filed together with a Notice of Appeal.

**REMARKS**

The Examiner has rejected Claims 1-6 as failing to comply with the written description requirement of 35 U.S.C. §112, first paragraph. The Examiner specifically asserts that the invention is directed to treating or ameliorating "inflammation," which, according to the Examiner, results from an unspecified disease or disorder, and no evidence is presented that a treatable disease was known to the Applicant at the time of filing. (10/11/06 Office Action, Page 2) The Examiner concludes, "[t]he instant specification simply fails to give an adequate description of the disorders or conditions that are associated with inflammation." (07/16/07 Office Action, Page 2).

Applicant respectfully disagrees with the Examiner's assertions. Applicant points out that there is a presumption of satisfying the written description requirement by the claims as

filed. Applicant points out that the Examiner does not meet the minimum burden explaining how it is one of skill in the art would not know Applicant was in possession of the claimed invention at the time of filing. Applicant further points out that one of skill in the art clearly understands inflammation to be a symptom associated with many stimuli, and one of skill in the art would understand that treating or ameliorating inflammation can be accomplished without necessarily knowing the underlying cause of the inflammation.

In response to the 10/11/06 Office Action, Applicant submitted remarks supported by well-established case law that to satisfy the written description requirement of 35 U.S.C. §112, first paragraph, the specification must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, Applicant was in possession of the invention as now claimed. (*Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991)) In addition, there is a strong presumption that an adequate written description of the claimed invention is present in the specification as filed, which includes the original claims. (*In re Wertheim*, 541 F.2d 257, 262, 191 USPQ 90, 96 (CCPA 1976)). Claims 1-6 of the instant matter are essentially original claims as filed and they should therefore benefit from a strong presumption that an adequate written description of the claimed invention is present in the specification as filed. The claims as filed were directed to preventing inflammation, and they were subsequently amended to treating or ameliorating an inflammatory disease. The scope of “inflammation” is identical in both the claims as filed and the amended claims. The presumption of adequate written description provided by the original claims as filed, therefore, certainly carries over to the amended claims, where only a slight modification to terms in the preamble was made. The very well-established case law stating that original claims provide a basis for satisfying the written description requirement, therefore, dictates that the written description requirement is met with regard to “inflammation.”

The Examiner has the initial burden of presenting by a preponderance of evidence why a person skilled in the art would not recognize in an Applicant’s disclosure a description of the invention defined by the claims. *Wertheim*, at 263; See also MPEP §2163.04. Applicant submits that the Examiner has not met his burden under 35 U.S.C. §112, first paragraph to challenge the adequacy of the written description of Claims 1-6 because Claims 1-6 should have a strong

presumption of an adequate written description in the application as filed, and the Examiner does not provide anything more than a conclusion that the written description requirement is not fulfilled. The Examiner alludes to the fact that inflammation is associated with many disorders and diseases and can occur in every part of the body (07/16/07 Office Action, Page 2). The Examiner then states that in the absence of a disease, the written description requirement is not met. The Examiner does not provide any reasoning in arriving at this conclusion. The fact that one of skill in the art would know that inflammation can have many causes and occur at many places in the body does not, in and of itself, warrant the conclusion that one of skill in the art would not be able to recognize a distinct treatable condition in the absence of knowing a specific disease or cause of that condition.

In fact, the Examiner's conclusion is not warranted as symptoms can clearly be treated without necessarily knowing the underlying cause of the symptom. Symptoms can be treated without reference to an underlying cause of the symptom. A lozenge can be used to treat, for example, a sore throat without knowing whether the cause is a cold, overexertion, smoking, etc. The requirement imposed by the Examiner that a description of diseases that cause inflammation demands too much. One of skill in the art would certainly recognize that regardless of the underlying cause, the symptom, inflammation, occurs by as known mechanistic response, and inflammation can certainly be treated without necessarily knowing the underlying cause. This recognition of the inflammatory response, as detailed in Applicant's response to the 10/11/06 Office Action and below, would allow one of skill in the art to realize that Applicant was in possession of the claimed invention at the time of filing, thereby satisfying the written description requirement.

"The descriptive text needed to meet these requirements varies with the nature and scope of the invention at issue, and with the scientific and technologic knowledge already in existence." (*Capon v. Esharr*, 418 F.3d 1349, 1357 (C.A.Fed., 2005)). Applicant submits that Claims 1-6 do not fail for lack of written description pursuant to 35 U.S.C. § 112, first paragraph because the claims are directed to a physiological process that was well-recognized by the artisan at the time the instant application was filed. As noted above, Claims 1-6 of the instant application are directed to "treating or ameliorating inflammation in an individual...". "Inflammation is the first

response of the immune system to infection or irritation and may be referred to as the innate cascade. Inflammation is characterized by the following quintet: redness (rubor), heat (calor), swelling (tumor), pain (dolor) and dysfunction of the organs involved (*functio laesa*). The first four characteristics have been known since ancient times and are attributed to Celsus; *functio laesa* was added to the definition of inflammation by Rudolf Virchow in 1858.”

(en.wikipedia.org/wiki/Inflammation). The PDR Medical Dictionary defines “inflammation” in part as a “**fundamental** process consisting of a dynamic complex of cytologic and chemical reactions...” [emphasis added]. The claimed method is therefore directed to treating or ameliorating a physiological response to tissue injury or insult, not a specific disease. Applicant has demonstrated that the inflammatory response is known to one of skill in the art and, because it is a fundamental response, it shares a common mechanism regardless of the underlying stimulus that leads to the response. One of skill in the art would recognize that generally treating the response can be accomplished regardless of the underlying stimulus. As such, Applicant submits that the Examiner’s conclusion that “[i]n the absence of understanding of the disease to be treated, the artisan would not have accepted that applicant was in possession of the claimed invention” is erroneous because the Examiner is not considering what was known and accepted in the art at the time of filing.

In light of these remarks, Applicant respectfully requests that the Examiner’s rejection of Claims 1-6 be removed, and that the claims be allowed to issue.

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Respectfully submitted,

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